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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,274	09/05/2002	Michael George Hunter	010180.00012	9431

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EXAMINER	
PATEL, SUDHAKER B	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,274	HUNTER ET AL.	
	Examiner	Art Unit	
	Sudhaker B. Patel, D.Sc.Tech.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' communication paper dated 2/11/2002 is acknowledged. The claims in this application are the claims 1-4.

First action on merits follows.

Priority

1. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in Application No.PCT/GB 99/02629 filed 8/10/1999 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be made in this application. In making such claim, applicant may simply identify the application containing the priority papers.

2. It is noted that this application appears to claim subject matter disclosed in prior Application No. 10134754, filed 4/30/02. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay

was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.
Examiner's Position: Based on initial search, the U. S. Application Sr. No. 10049274 filed 9/5//02 will be considered for priority date which is the filing date of this application i.e. 9/5/02.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 2/11/02 is being considered by the examiner. See rejections bellow. Signed copy of PTO Form 1449 is enclosed with this communication for applicants' record.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim1 is rejected under 35 U.S.C. 101 because either a process or step asserted utility or a well-established utility does not support the claimed invention.
Claims drafted in terms of "use" are held to be nonstatutory. Note Clinical Products v. Brenner 149 USPQ 475.
Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an exact step/process of administration asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and/use the claimed invention. See rejections bellow.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
(A). Claims 1,4 recite variables as heterocyclic or aryl. It is not very clear as to what is exactly excluded from such recitations. Is heterocyclic ring aromatic in nature? What is included by aryl? Is anthracene excluded from aryl-?
(B). Claims 1,4 recite:" compound of Formula (I) and pharmaceutically and veterinarily acceptable salts, hydrates and solvates thereof". Corrections to:" compound of Formula (I) or pharmaceutically and veterinarily acceptable salts or hydrates or solvates thereof" is required.
(C). Claims 1,4 recite variables R5 and R6 when taken together with N atom to which they are attached form an optionally substituted saturated heterocyclic ring of 3-8 atoms

which ring is optionally fused to a carbocyclic or second heterocyclic ring". What is included in the second heterocyclic ring?
(D). Claims 2,3 recite bacterial infections and bacterial contamination. What is excluded from the claims?
7A. Claims 1,4 are rejected as failing to comply with 37CFR 1.141(a). The claims are more than a reasonable number of species.37CFR 1.141(a). Provides for a reasonable number of species to be examined with the genus. Claims 1 is an aggravated, multiple page (pages 41-44) consisting of more than 25 compounds with different molecules), and examples of listing ultimate species in one claim. Claim 1 is not Markush claim, see claims 4 and is listing of ultimate species to save the application fees.

Applicants are reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see e.g. In re Van Guens, 988 F. 2d 1181, 26 PSPG 2d 1057 (Ded. Cir. 1991). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-4 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6423690. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '690 patent anticipate the instant claims. A claim drawn to a method of using a compound anticipates a claim drawn to the compound per se.
10. Claims1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6441042. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the significant degree of overlap between the generic formulae of the claimed method of the '042 patent and the instant claims. The claimed method of the '042 patent have the same substituents (see claims 3,6,7,10,11,and 15) as do the

instant claims, and because of the similarity in anti-bacterial activity, the compounds recited in the instant claims are deemed to be obvious over the claims of the '042.

11. Claims 1-4 are provisionally rejected under the judicially created doctrine of double patenting over claims 27-43 of copending Application No. 10134754, filed 4/30/2002. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Instant claims 1-4 overlap with the ref. claims 27-31,33-40. Instant claims 1,4 do not recite variable IB & variable IC of the ref.'754. However, if the instant case were to be granted a patent, it would extend the patent life of the co-pending application upon patenting the same.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fournie-Zaluski et al (J.Med.Chem. 28,1158-69(1985)). Fournie-Zaluski teaches compounds at Table I in page 1162. See in particularly compounds 7.9.and 10, wherein instant A variable is IB. The ref. compounds are administered intracerebroventricularly as claimed herein. See page 1164 and Figure 9. Note that an intended use limitation does not impart patentability to product or composition claims where the product or composition is otherwise anticipated by or obvious over the prior art(s).

14. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 97/38705 dated 10/1997. The WO Patent Application '705 teaches compounds 13-17 at page 56 which have Applicants' claimed structures in which instant A – instant IB. The compounds are administered in combination with a pharmaceutically acceptable carrier (see e.g. claim 12).

15. Claims 1-4 rejected under 35 U.S.C. 102(b) as being anticipated by Handa et al (U.S.P. 4996358). Handa teaches a compound at column 5, lines 21-22, which as instantly claims structure wherein instant A is IB. The compounds of Handa et al are administered as claimed herein (see e.g. column 10, lines 34-47).

16. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 94/10990. The WO Patent Application '990 teaches compounds 96,97 (see page 26) which anticipate Applicants' claimed compounds in which A is IB.

The compounds are administered as claimed herein (see pages 14-15), e.g. to treat acute infection, septic shock, sepsis syndrome, mycobacterium infection, and meningitis (see, e.g. claims 20 and 21).

17. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jin et al (Bioorg. Med. Chem. Letters 8/24,1158-69(1998)). Jin teaches compound of Table I e.g. L1-3, D1-3, compounds 4,5, which overlap with the instant claims.

Claim Rejections - 35 USC § 112

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 2-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite generic methods of treatment of bacterial infections and bacterial contaminations respectively.

20. In cases directed to chemical compounds, which are being used for their physiological/biological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. See in re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group and In re Wiggins 179 USPQ 421.

21. "Compound or pharmaceutically acceptable salts or veterinarily acceptable salt, hydrates or solvates thereof" as recited in the claims read on all such moieties regardless of complexity of structure and point of attachment to the aliphatic or carboxylic or aromatic or heterocyclic core or bridge/chain for which there is no sufficient teaching how to make and how to use at any one selective location among the many possible sites present. The situation is more confusing when a skilled person in the art tries to visualize the multiple possibilities of combining a compound of claims 1, 4(or claims dependent on them) and/ or its pharmaceutically/veterinarily acceptable salts for treating a patient having diseases or conditions which are mediated by cytokines/ receptors in general. Applicants provide no reasonable assurance that any and all derivatives of the instant compounds and their use as outlined, will have ability to generate the compounds in vivo or in vitro by one or more processes.

22. In evaluating the enablement question, several factors are to be considered. In re Wands, 8 USPQ 2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include:***(1).*** The nature of invention;***(2).*** the state of prior art ;***(3).*** the predictability or lack thereof in the art; ***(4).*** the amount of direction or guidance present;***(5).*** the presence or absence of working examples;***(6).*** the breadth of the claims, and ***(7).*** the quantity of experimentation needed.

1). The nature of the invention: The compounds and their method of use claim(s) are drawn in part to use them for treating bacterial infections in humans and non-human mammals, and bacterial contamination, and infections yet to be discovered.

2). The state of prior art: There are no known compounds of similar structure (i.e. compounds of the invention that have been demonstrated for the treatment of bacterial infections in humans and non-human mammals, and bacterial contamination as recited here in a generic way.

3). The predictability or lack thereof in the art: It is presumed in the use for patient(s) who are humans or animals suffering from infection(s) related to a generic bacterial activity as claimed herein, there is a way of identifying those patient(s) who may develop any kind of bacterial infection(s), and get involved in bacterial contaminations including (but not limited to) a single infection. There is no evidence of record, which would enable the skilled artisan in the identification of the patient(s) who have the potential of becoming afflicted with the bacterial infections and bacterial contamination as claimed herein.

4). The amount of direction or guidance present and 5).: The presence or absence of working examples: There are no doses present to direct one to treat a potential host from an infection or contamination, and other multiples of infections related to various types of bacteria. Specification remains silent about the exact patient-dosage regime, and claims also remain silent about the exact method or step of administration for treating such diseases.

6). The breadth of the claims: The claims are drawn to bacterial infections and contaminations (not limited to) and not for treatment of a single, specific and exact infection/contamination which are not related and whose treatment(s) is unknown by a single compound of instant invention.

7). The quantity of experimentation need would be and undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan for the many reasons stated above.

23. ***Discussion about bacteria:***

24. **Authors' admission of facts as per instant specification (see pages 1-2):** although the substrate specificity of peptide deformylase (PDF) has been extensively studied, the identity of the metal binding group and its spacing from the rest of the molecule ("recognition fragment") has not been studied in a similar way. Additionally, non-peptidic PDF inhibitors, which may be desirable from the point of view of bacterial cell wall permeability or oral bioavailability in the host species, have not been identified. Total eradication of gram-positive as well as gram-negative organisms by antibacterial agents by a single compound is a very difficult task because of the evolution of emergence of multidrug-resistant bacterial pathogens.

25. ***Discussion about some of bacterial infections:***
26. Cystitis is an infection of bladder, usually caused by bacteria. Blepharitis is a chronic inflammation of the eyelids that is caused by a staphylococcus. Dacryocystitis is inflammation of the tear sac, and usually occurs after a long-term obstruction of the nasolacrimal duct and is caused by staphylococci or streptococci. Preseptal cellulites is inflammation of the tissues around eye, and Orbital cellulites is an inflammatory process involving the layer of tissue that separates the eye itself from the eyelid. These life-threatening infections usually arise from staphylococcus. Hence, these types of inflammations are treated with antibiotics.
27. ***Following some of the many references are cited to show the sate of art related to peptide deformylase and its antibacterial properties:***
28. **Challenges in antimicrobial drug discovery and the potential of nucleoside antibiotics:** Rachakonda et al (PubMed Abstract 15032731, also cited as Curr. Med. Chem. 11/6,775-93(2004)) state that:" More detailed investigations on the structure, as it relates to antimicrobial activity of various classes of nucleosides, need to be conducted in order to maximize the potential of developing a potent nucleoside for the treatment".
29. ***In vitro antibacterial activity of the PDF inhibitor BB-83698:*** Lofland et al(PubMed abstract 14973152, also cited as J. Antimicrob Chemother. 53/4,664-8(2004)) state that:" Although BB-83698 has reduced in vitro activity against H. influenzae, it is a potent antimicrobial with excellent activity against streptococci and Moraxella".
30. **Oral anti-pneumococcal activity and pharmacokinetic profiling of a novel peptide deformylase inhibitor:** Gross et al(PubMed Abstract 14963065, also cited as J. Antimicrob. Chemother. 53/3,487-93(2004)) state that:" BB-81384, a novel PDF inhibitor with good activity against S. pneumoniae in vitro, was ***the FIRST*** compound of this class to be profiled for oral pharmacokinetics and tissue disposition and to demonstrate oral anti-pneumococcal efficacy in mice". Specification remains silent about such a performance by the instantly claimed compounds.
31. **VRC3375, a proline-***3-alkylsuccinyl hydroxamate derivative:* Chen et al(PubMed Abstract 14693547, also cited as Antimicrob. Agents Chemother. 48/1,250-61(2004)) state that:"Pharmacokinetic studies of this drug in mice indicate that VRC3375 is orally bioavailable and rapidly distributed among various tissue. It ha in vivo activity against S. aureus in a murine septicemia mode with 50% effective doses of 32, 17, and 21 mg/kg of body weight after dosing intravenous (i.v.), subcutaneous (s.c.), and oral (p.o.) administration, respectively". The instant specification does not teach such findings for the compounds and their utility as claimed herein.
32. ***N-alkyl urea hydroxamic acids as a new class of PDF inhibitors with antibacterial activity:*** Hackbarth et al (PubMed Abstract 12183225, also cited as Antimicrob. Agents Chemther. 46/9,2752-64(2002)) state that:" VRC 4307 has a binding position similar to that previously determined for succinate hydroxamates. It displayed in vivo efficacy in a mouse protection assay, with 5 protective doses of 30.8 and 17.9 mg/kg of body weight, respectively. These alkyl urea hydroxamic acids provide a starting point for identifying new PDF inhibitors that can serve as antimicrobial agents".

33. Specification in pages 37-40 recite various testing/assay methods. By way of:" Demonstration of antibacterial effect", and in page 40 line11 the results are summarized as:" The compounds of the invention were found to inhibit bacterial PDF in vitro".
34. These results will only serve for the preliminary screening of many compounds, and not for treating the diseases as claimed herein.

The facts as provided above do support the need for additional quantity of experimentation, which would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the method of treatment for various infections, and other diseases.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of instant compounds to treat various infections as recited in specification only.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs. Novo Nordisk*, 42 USPQ2nd 1001, 1006.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is (571) 272-0671.

The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on (571) 272 0674 or Sr. Examiner Mr. Richard Raymond at (571) 272 0673 or Mr. James Wilson at (571) 272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status

information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sudhaker B. Patel, D.Sc. Tech.
May 16, 2004

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